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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,506	04/18/2006	Shawn DeFrees	040853-02-5144US01	6231

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EXAMINER
HA, JULIE

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
04/16/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,506	DEFREES ET AL.	
	Examiner	Art Unit	
	JULIE HA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-33* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

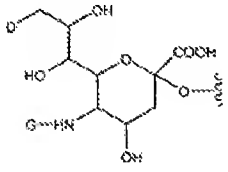
DETAILED ACTION

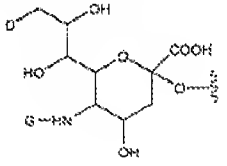
Election/Restrictions

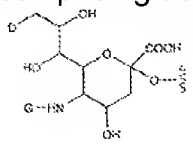
1. Restriction is required under 35 U.S.C. 121 and 372.

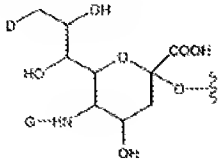
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

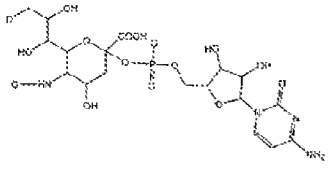
In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

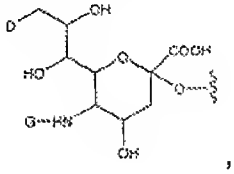
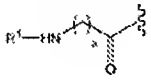
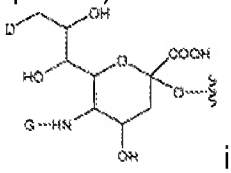
Group 1, claim(s) 1-15, drawn to a factor IX peptide comprising at least one moiety having the formula  and a pharmaceutical composition comprising the factor IX.

Group 2, claim(s) 16, drawn to a method of stimulating blood coagulation in mammal, said method comprising administering to said mammal said factor IX peptide of formula  .

Group 3, claim(s) 17, drawn to a method of treating hemophilia in a subject, said method comprising administering to said subject said Factor IX peptide of formula  .

Group 4, claim(s) 18-33, drawn to a method of making a Factor IX peptide conjugate comprising the moiety  , wherein the method comprising: (a) contacting

a substrate Factor IX peptide with a PEG-sialic acid donor moiety having the formula  and an enzyme that transfers said PEG-sialic acid onto an amino acid or glycosyl residue of said Factor IX peptide, under conditions appropriate for the transfer.

2. The inventions listed as Groups 1-3 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The Factor IX peptide comprising at least one moiety having the formula  , wherein D is OH, G is R^1-L- having the formula  is disclosed in US Patent No. 7,179,617 (see Scheme 12). US Patent No. '617 teaches remolding and glycoconjugation of Factor IX (see Title, abstract, and throughout the patent). The special technical feature of Factor IX peptide conjugated to formula  is known in the art. Therefore, unity of invention is broken.

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process

claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election of Species

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Different variables: R1, D, G, L, e, f, q, f', q', q", a, b, c, d, l, r, s, t, u, g, h, j, k, l, m, v, w, x, y, AA;

Different formula moiety: from claims 7-9 and 13;

Different amino acid residue: serine or threonine;

Different Sia(R) formula due to different variables: D, G, R1, L;

Different sites of attachment of glycosyl residue: Asn 157 or Asn 167;

Different enzyme that transfers PEG-sialic acid onto an amino acid or glycosyl residue: for example, from paragraph [0012] of instant specification US 20080318850;

Different host: insect cell or mammalian cell.

5. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

6. If Group 1 is elected, Applicant is required to elect a single disclosed species of one moiety having a single disclosed species of a formula (all of the variables elected to arrive at a single disclosed species of a compound), if an amino acid is involved in the compound structure, the amino acid residue, the Factor IX sequence (species), and the attachment site of glycosyl residue, for example, Asn157. If Group 2 is elected, Applicant is required to elect a single disclosed species of one moiety having a single disclosed species of a formula (all of the variables elected to arrive at a single disclosed species of a compound), and the Factor IX species. If Group 3 is elected, Applicant is required to elect a single disclosed species of one moiety having a single disclosed species of a formula (all of the variables elected to arrive at a single disclosed species of a compound), and the Factor IX species. If Group 4 is elected, Applicant is required to elect a single disclosed species of one moiety having a single disclosed species of a

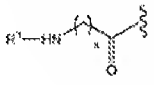
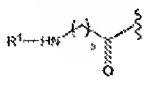
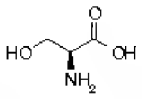
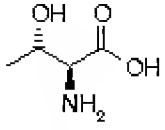
formula, substrate Factor IX peptide species, a species of PEG-sialic acid donor moiety, a species of an enzyme, amino acid or glycosyl residue, host cell. If an amino acid residue is involved in the structure of moiety compound, then please elect a single disclosed species of an amino acid residue, for example, serine.

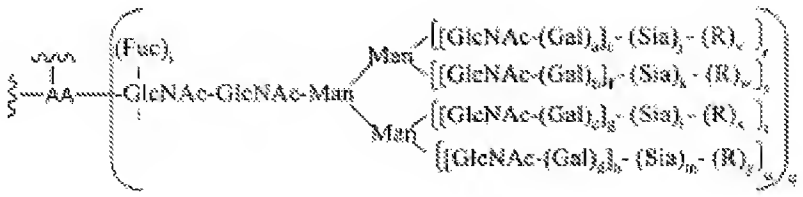
7. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

8. The claims are deemed to correspond to the species listed above in the following manner:

Claims 2-12, 14, 19-29, 31

The following claim(s) are generic: Claims 1, 13, 15-18, 30, 32-33.

9. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Different compound of formulae moiety are patentably independent and distinct due to different variables, leading to different structures. For example, a moiety having D is OH and G having  is different from D is  and G is –C(O)(C_1-C_6)alkyl. Different variables are patentably independent and distinct due to their different structures. Further, search for one would not necessarily lead to the other. Different moieties having different formulae are patentably independent and distinct due to different variables involved in the moiety. Further, search for one would not necessarily lead to the other. Different amino acid residues are patentably independent and distinct due to different structure of the residues. For example, serine has the structure  and threonine has the structure  . Further, search for serine would not necessarily lead to a threonine and vice versa. Different moieties of



formula are patentably independent and distinct due to the different variables involved (such as Sia-(R)), leading to patentably independent and distinct structures. Further, search for one would not necessarily lead to the other. Different sites of attachment of glycosyl residue are patentably independent and distinct due to different sites that glycosyl residue can be attached to. For example, there are multiple Asn sites on the peptide Factor IX (see for example, GenBank AAA98726). Furthermore, a Factor IX sequence from human is different from other species (see GenBank CAA01607). Search for one would not necessarily lead to the other. Different enzymes are patentably independent and distinct from each other due to different structures and different function. For example, sialyltransferase are enzymes that transfer sialic acid; N-acetylglucosaminyltransferases catalyze the transfer of N-acetylglucosamine from a nucleoside diphosphate N-acetylglucosamine to an acceptor molecule which is frequently another carbohydrate (see definition from http://www.online-medical-dictionary.org/N-Acetylglucosaminyltransferases.asp?q=N-Acetylglucosaminyltransferases, enclosed). Further, search for one would not necessarily lead to the other. Different cells are patentably independent and distinct due to the source and the different types of reagents and experiments required. For example, insect cells and mammalian cells are patentably independent and distinct. Insect cells are often used to express proteins that are post translationally modified only in eukaryotic cells (e.g., glycosylation) (see http://www.biochem.northwestern.edu/holmgren/Glossary/Definitions/Def-I/insect_cells.html). Mammalian cells include human, rodent, primate and other cells derived from mammals. Further, search for one would not necessarily lead to the other.

10. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

11. The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does

not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

13. **Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.**

14. **Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.**

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE HA whose telephone number is (571)272-5982. The examiner can normally be reached on Mon-Thurs, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Julie Ha/
Examiner, Art Unit 1654